# EXHIBIT J

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION
MDL DOCKET NO: 1629
Master File No. 04-10981

THIS DOCUMENT RELATES TO:

ALL PRODUCTS LIABILITY ACTIONS

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| VIDEOTAPED DEPOSITION OF: | CHERYL D. BLUME, Ph.D. |
| DATE: | November 12, 2007 |
| TIME: | 9:25 a.m. to 6:07 p.m. |
| PLACE: | 13902 North Dale Mabry Highway<br>Suite 122<br>Tampa, Florida |
| PURSUANT TO: | Notice by counsel for Defendants for purposes of discovery, use at trial or such other purposes as are permitted under the Federal Rules of Civil Procedure |
| BEFORE: | VALERIE A. HANCE, RPR<br>Notary Public, State of Florida at Large |
| | Volume 1<br>Pages 1 to 370 |

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THE VIDEOGRAPHER: This is the videotaped deposition of Cheryl Blume, Ph.D., being held in the offices of Pharmaceutical Development Group located at 13902 North Dale Mabry Highway in Tampa, Florida, on November 12th, 2007. The time is 9:25 a.m.

My name is David Leggett. I'm the videotape specialist. And the court reporter is Valerie Hance. Will counsel introduce themselves.

MR. BARNES: Richard Barnes on behalf of Pfizer.

MR. GUNTER: Vince Gunter on behalf of Pfizer, defendants.

MR. WASICKO: Michael Wasicko on behalf of Pfizer.

MR. FROMSON: Kenneth Fromson on behalf of the product liability plaintiffs in the MDL, liaison counsel in the New York coordinated litigation, and counsel for plaintiffs in the action of Nicolette Crone vs. Pfizer, Lake County, California.

MR. ALTMAN: Keith Altman, nonattorney with Finkelstein & Partners.

MR. BARNES: Counsel on the phone, please identify themselves.

MS. DALEY: Annamarie Daley, counsel for

necessity during different time periods.
I believe the first time period that we will be interested in is in the period 1994 to 1996. And I'll get to that in just a second.
Now, the adverse events that are noted in this report that appear in either quarterly or annual reports or in PSURs, we are able to access those and address those in our office.
Where I turn to Mr. Altman's expertise are in the -- are in the large databases that are relied upon in doing -- conducting pharmacovigilance work. So that would include the Pfizer's -- Pfizer's internal database. And, for example, he would have been involved in the work that we did in -- the first time period of relevance is '94 to '96.
Q. Would you please tell me the charts which he pulled for you, please.
A. He filtered the data that would have been involved in -- on page 69 of my report, page 70, 71, 72, which are the filter of the top 25 adverse events during that relevant time period in the database across all body systems. And that would proceed to 72, 73, 74.
Beginning on page 75, which is paragraph 117, we turn then to the various available databases, independent available databases. During this timeframe



with the U.S. Government, it would have been the SRS --
Q. Who did --
A. -- system.
Q. Who -- who pulled the data on -- and did the analysis for paragraph 117 on page 75?
A. Mr. Altman.
Q. Mr. Altman did?
A. Yes. This is from the FDA's database. It's maintained by -- I think it's maintained by NTIS.
Q. So just so I understand, the tables on 69, 70, 71, 72, 73, 74, and page 75 were prepared by Mr. Altman, correct?
A. He provided me with the numbers of events. The tables were actually prepared here.
Q. What did you do -- let's just take page 75. What -- describe what you personally did to prepare Table -- the table on page 75.
A. Okay. This is in 1994, which would have been the first marketed year of Neurontin in the United States, so Pfizer would be submitting quarterly reports during that timeframe. So we pulled the terms that we were interested in having filtered by Mr. -- Mr. Altman from the FDA's database. We gave him the terms that we were interested in. He gave me the number of reports.



I also asked him to give me the total number of events in the database so we could do the standard calculation of the percent of total.
Q. So on page 75, you look at abnormal dreams, that -- that percentage, the numerator is -- let's say on 1996 Q2, the numerator would be one, and then the denominator would be all events in the database pertaining to having been reported to Neurontin?
A. That would be yes.
Q. Okay.
A. Oh, yeah. And it would only be the Pfizer database, of course, because it was a sole source product at that time.
Q. Okay. Continue after '75 as to what -- what Mr. Altman prepared versus to what -- as to what you prepared.
A. Okay. So the --
Q. Who accessed Health Canada on page 76?
A. Well, that's World Health Organization.
Q. I'm sorry.
A. That's not Health Canada.
Q. I made a mistake. I apologize.
A. We generally access the WHO database. Now, whether we did it in this case or Mr. Altman accessed it, I don't specifically recall.



Q. You don't know who prepared this. Who provided the terms?
A. We provided the terms.
Q. You directed the terms and he went -- he or you -- on this, on page 76 -- went into the database to extract it?
A. Yes, it's a little different with the World Health Organization. When you receive the database from them, they send you the entire database, so it's a matter of going through and extracting from a whole -- you don't -- you don't have the opportunity to do it by body systems. They send you everything.
Q. Do you have -- okay.
Do you have the database that was provided to you from World Health Organization in your possession; that was used to create this table on page 76?
A. Yes, and I have put that on this disk as well.
Q. And that would be referring to Exhibit No. 3?
A. Yes.
Q. Thank you very much.
All right. Why don't you continue to review the report just as to what you -- so -- what you prepared.
Right now, we have Mr. Altman preparing 69, 70, 71, 72, 73, 74, 75, and 76, correct?

MR. FROMSON: Just note my objection as to the form in terms of the use of the word "prepare."
MR. BARNES: "Filtered" was her room -- word. "Filtered." I'll --
THE WITNESS: Yes. And just to clarify, I would have to check if we -- if we did the World Health Organization or if he did it.
BY MR. BARNES:
Q. You'll check on that for me?
A. Yes, I will.
Q. Okay. Now, when you -- Mr. Fromson noted an objection. What do you mean by Mr. -- by using the phrase Mr. Altman filtered the information for you, what does that mean?
A. Well, my understanding of the FDA and some of these other databases is they are huge databases. The word "filter" is simply my way of asking him to apply the rules and the conditions that he has established in evaluating the database and calculating the number of specific events at -- at this designated time periods.
Q. What are the rules that Mr. Altman established in querying the databases to get the number of events?
A. Well, we out -- we outline these. When we submit, for example, to the Food and Drug Administration, we give a complete list of what he does.



But my understanding is that care is taken to take into consideration when there is an initial report versus a follow-up report so it is not counted twice. We filter -- I believe he filters the database so that we are getting all of the information. We take the last reports so that it includes all the cumulative information. He checks for duplicates. He is able to filter them for us by suspect status, nonsuspect status. If we ask, he can filter it by various demographics. For example, if the patient were on other meds, were not on other meds.
If we're given information generally, whatever fields -- it is my understanding, whatever fields are in the intake form, he would be able to filter by those forms -- fields. Excuse me.
Q. Are you -- is it your testimony that that's what he did in this case?
A. Well, what I asked for -- and there are certain -- there are certain precautions that he undertakes for all tables. For example, he is very careful that we don't double count. He is very careful that we put the event when the event was -- when the event occurred, not necessarily when reported.
Q. How do you know he was careful? What did you do to -- did you do anything to audit his work in this



case to verify that he was exercising care?
A. We have used his -- the method that he has developed has been provided to the FDA. FDA has queried him independently on the way in which he analyzes these data. FDA has -- has approved our applications using these data. I understand that Mr. Altman communicates with the FDA on projects other than mine, as well, on these database assignments, so --
Q. My question is, what did you do in this particular case to verify that Mr. Altman exercised care in preparing these tables and filtered it in an accurate and reliable way --
A. Well, I under --
Q. -- in this case?
A. Yes. I understood he used the same system that has been previously found to be acceptable. I cannot tell you over the last four years of whether I did any other independent checking or not. I just don't recall.
Q. In this case, did you do any independent checking of Mr. Altman?
A. That's what I'm saying. In the last four years, I just don't recall if I did or not.
Q. Well, when were you retained in this matter?
A. 2003. 2003, I think.



Q. 2003.
And who called you?
A. Wow. I think I was contacted by Andrew Finkelstein.
Q. Okay. So is there any documentation that you have reviewed to verify that the material provided to you and the analysis provided to you by Mr. Altman was done in -- in a scientifically-rigorous and reliable manner?
MR. FROMSON: Just note my objection as to form.
THE WITNESS: I -- over the years, I don't recall if I did any of that on this case. I accept his work because it has been accepted and -- and validated to FDA satisfaction.
BY MR. BARNES:
Q. Would you de- -- would you please describe to me the -- the cases that Mr. Altman worked -- Mr. Altman's work has been validated by the Food and Drug Administration.
A. Well, I -- I can tell you that NDAs have been approved using his database work, but I -- it's the same answer I gave you earlier. I can't identify those clients.
Q. Has any of Mr. Altman's work been published in

Q. Is -- are -- is -- is -- are the analyses that Mr. Altman prepared for you, as you've defined it in this litigation, important to your opinion in this case?

MR. FROMSON: Just note my objection as to the form. That's an ambiguous question.

THE WITNESS: Well, I think that everything I have in here is important. I mean, the World Health Organization database is important to me. Yes, they're all important to me.

BY MR. BARNES:

Q. So if -- if Mr. -- is it your testimony that if you extracted the SRS database analysis and the analysis based on the internal Pfizer databases that your opinion would be the same with regard to the signal analysis?

A. Well, the Pfizer database was also repeated in the 2004 NDA records. So, I mean, even if I lost the Pfizer databases, I would still have their analyses of those databases in the NDA submission.

Yeah, my opinion would still be the same, because there -- there was an amazing similarity in signals and conclusions across SRS and WHO and even the Health Canada database.

Q. Just so I understand though, you -- so your -- the absence -- you do not need the SRS database analysis



to form your opinions with regard to signals?

A. Well, it's almost an impossible question to answer. We are required to assess the SRS database for signals. I mean, FDA has criteria on how one data mines the database. So, yes, it's important to me, but we additionally mined the WHO database and we looked at the mining efforts of your client in their internal database and in the materials they redid in 2004. So my opinion is not dependent on any one issue.

And if, as you read the conclusions, I go across -- I conduct pharmacovigilance across databases, not dependent on one database. Now, if one database were remarkably different than the other one, we might go back and check that again.

Q. Okay. Let's move on. One --

A. What page are you on?

Q. 120, I think, is my next table. Who prepared that?

A. This is the internal database, and I believe this was Mr. Altman on through 120 -- let's see -- 127.

Q. So from 120 to 127 are various tables of reports of adverse events that Mr. Altman extracted from the Pfizer internal database between 1996 and 2002, correct?

A. Yes.



Q. And, again, did you audit or in any way validate the work product you received from Mr. Altman on pages 120 to 127?

A. No.

Q. Okay. What's on 128? This is PSURs, annual reports? Or is this the internal Pfizer adverse event database?

A. No, this is not -- this isn't PSUR. These are -- this is the internal database.

Q. So then, again, this is Mr. Altman's work, correct, on 128?

A. Yes. And these are for -- well, in part.

Your client did a partial amplification of their label in '96 to include some additional postmarketing events. And the ones listed on the page are the ones that Pfizer chose to put into the package insert at that timeframe.

Q. You say the word "Pfizer" in 1997. Is it your testimony that Pfizer, Inc., modified the label in 1997?

A. Well, I think they -- I'm using "Pfizer" to refer to them all. I think Pfizer came in around 2000, but when I say "Pfizer," I'm referring to Parke-Davis and Warner-Lambert.

Q. Is it important to you to be accurate in the way you -- you testify in terms of what corporation,



what party conducted certain analyses?

A. I think in the report I talk about the different -- who submitted the different reports, when they were submitted, at different time points. But for the purposes of discussion, I have been just using the term "Pfizer."

Q. Well, for purposes of this deposition, when I use the term "Pfizer" and I use the term "Parke-Davis/Warner-Lambert," they're two different corporations. Do you understand that?

A. I do, but I also looked in the database and couldn't find anywhere when Pfizer did -- did assume control that they corrected anything that Parke-Davis did.

Q. That's not -- that's not the question.

A. So since that time, I have just referred to everything as "Pfizer."

Q. Well, what -- so is it your view that you just lump everybody together no matter who's actually involved as a matter of fact?

MR. FROMSON: Just note my objection as to form.

THE WITNESS: I don't -- I don't understand.

BY MR. BARNES:

Q. Well, when you say the word -- when you say

products as percent reports. Both of these tables were done by Mr. Altman.

Q. Who directed that these tables be prepared?

A. The table in 194 is a table across comparisons of different antiepileptic drugs. It's a standard way that we have tried to pictorially present the data that we looked at earlier in comparison to other sister drugs. I asked that that be done.

Q. And so you directed this analysis?

A. Yeah, this is a routine analysis for us in our work when we're -- when we have drugs that are part of a class.

And I had -- page 195 is a comparison from another trial -- another project that I guess Mr. Altman is working on. But it illustrated the same sort of separation within a class.

Q. So Mr. Altman prepared this chart on page 195, correct?

A. Yeah, well, he did 194 and 195.

Q. Did both of them?

A. Right.

Q. Okay. Did you do any independent work to validate the graph on page 194 or on page 195?

A. No.

Q. And so you don't know if there is a rate of



error for the data depicted on page 194 which is entitled "PRR Over Time, Suicidal and Self-Injurious Behavior HLT," correct?

A. I don't know if there is any rate of error and I --

Q. One way or the other?

A. I don't have a -- no, I did not validate it.

Q. Did you -- did you -- you said something about this is how -- at page 194, 195 -- this is how you routinely do these analyses for other -- other clients?

A. No, for pharmacovigilance work.

What this does is, we're interested in this case in Neurontin, so Neurontin will be on the chart, but as pharmacovigilance assignments, you're always interested if a particular adverse event is simply part of the -- is part of what is observed with that class of drugs or whether there is something unique with --

(Phone ringing.)

THE WITNESS: Somebody is calling in.

-- whether there is something unique with your drug.

So what one does, what we are -- what is suggested, what we are taught to do is to do these PRR ratios. Because if there is something unique



about a drug, it will look different in a PRR time, time-derived data, than will the other drugs in the class.

BY MR. BARNES:

Q. Who chose the drugs on page 194 for comparison?

A. Oh, I -- I don't know if we did these. I -- I think I mentioned in my report Gabitril. I know we talk about carbamazepine. I don't -- I don't know if we did that collectively or if I sent the list one. I don't know.

Q. So it's possible that Mr. Altman chose the comparator drugs --

A. Well --

MR. FROMSON: Just note my objection.

BY MR. BARNES:

Q. -- on this graph?

A. I --

MR. FROMSON: I'm sorry. Just note my objection as to form.

THE WITNESS: I don't recall how we did this. We had to do it in a -- we had to pick drugs that would have data across the relevant time period, so we couldn't use an -- an AED that were approved in 2003 or 2004, because it wouldn't have the data.



So I -- I don't -- whether we collectively did this or not, I just don't recall.

BY MR. BARNES:

Q. So it's possible that Mr. Altman chose the comparator drugs, correct, without your supervision?

MR. FROMSON: Note my objection as to form.

THE WITNESS: I recall the discussion of including Gabitril in there. I know that I remember that. Now, I just don't recall.

BY MR. BARNES:

Q. You say "class of drugs." What do you mean by a class of drugs?

A. Well, when you look at pharmacovigilance data, you're interested, of course, in the -- in the drug in question for that particular NDA, but you're also interested in other drugs that are chemically similar to that drug, whether it's used for the same indication or not, so you do that comparison. You compare the adverse event of interest with other drugs that are approved for the same indication, and you also approve drugs that have the same mechanism of action. So there is different ways that you canvas pharmacovigilance data.

In this particular table or this particular graph, what we have here are the PRRs for the suicide-related events, the high-level term